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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,612	04/27/1999	BINIE V. LIPPS	FWLPATU012	4662

7590 09/08/2004

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/300,612

Applicant(s)

LIPPS ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7-10,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7-10,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>3/25, 31, 4/8, 6/15/04</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

Amendment

1. The amendments filed on 10/20/03, 1/07/04, 4/08/04 and 6/17/04 have been entered into the record.

Status of Claims

2. Claims 5 and 7-19 are pending in the application.
Claims 5, 7-10, 15-16 have been amended.
Claims 11-14, 17 and 18, 19 have been cancelled.
Claims 5, 7-10 and 15-16 are currently under examination.

Objection Withdrawn

3. In view of amendment to the claims and cancellation of claim 14, the objection of claims, 5, 9, 11 and 14 is withdrawn.

Rejections Withdrawn/moot

4. In view of amendment to the claims and cancellation of claims, the rejection of claims 5, 7-10, 15-16 under 35 U.S.C. 112, second paragraph is withdrawn.
5. In view of cancellation of claims, the rejection of claims 11- 13 under 35 U.S.C. 102(b) as being anticipated by Sanchez et al 1998 (Toxicon: 36: 1451- 1459 in light of Farah et al 1996, Toxicon: 34: 1067- 1071) is moot.
6. In view of amendment to the claims and cancellation of claims 14, the rejection of claims 5, 7-8 and 15-16 under 35 U.S.C. 103(a) as being unpatentable over Sanchez et al (Toxicon: 36: 1451- 1459 in view of Harlow and Lane 1988) is withdrawn.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

Art Unit: 1645

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 5, 7-10 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for detecting a toxin or free toxin in a biological sample, said process comprising (a) contacting a biological sample with antibodies raised against a synthetic peptide consisting of SEQ ID NO: 1 or synthetic peptide LTNF -10 (peptide consisting of first 10 amino acids SEQ.ID.NO: 1) or against a natural 68 kDa Lethal Toxin Neutralizing Factor protein said protein is isolated from opossum serum (b) detecting the immune complex formed between the toxin and the antibodies by ELISA, does not reasonably provide enablement for a process for detecting a toxin or free toxin in a biological sample, said process comprising (a) contacting a biological sample with antibodies raised against at least five amino acids of SEQ.ID.NO: 1 (viewed as any random five amino acids of SEQ.ID.NO: 1) (b) detecting the immune complex formed between the toxin and the antibodies by ELISA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a process for detecting a toxin or free toxin in a biological sample, said process comprising (a) contacting a biological sample with antibodies raised against a synthetic peptide consisting of at least five amino acids of SEQ ID NO: 1, or against a natural 68 kDa Lethal Toxin Neutralizing Factor protein, said protein is isolated from opossum serum (b) detecting the immune complex formed between the toxin and the antibodies by ELISA.

The specification teaches only a process for detecting a toxin or free toxin in a biological sample, said process comprising (a) contacting a biological sample with antibodies raised against a synthetic peptide SEQ ID NO: 1, or synthetic peptide LTNF-10 consisting of first ten

Art Unit: 1645

amino acids of SEQ.ID.NO: 1 or against a natural 68 kDa Lethal Toxin Neutralizing Factor protein, said protein is isolated from opossum serum (b) detecting the immune complex formed between the toxin and the antibodies by ELISA. The specification is silent concerning, a process for detecting a toxin or free toxin in a biological sample, said process comprising (a) contacting a biological sample with antibodies raised against at least five amino acids of SEQ.ID.NO: 1 (viewed as any random five amino acids of SEQ.ID.NO: 1) (b) detecting the immune complex formed between the toxin and the antibodies by ELISA.

The specification and the state of art (U.S.Patent 5,744,449) indicate that the antibodies raised against antigen LTNF-n, LTNF-15 and LTNF-10 bind to LTNF-n, LTNF-15 and LTNF-10 and to the toxin obtained from various biological samples (see the table below from (U.S.Patent 5,744,449)

TABLE VIII

<u>Binding Affinity of Venoms and Toxins to Anti LTNF-n and LTNF-s by ELISA</u>			
Antigen	<u>ELISA Antibody Titer</u>		
	LTNF-n	LTNF-15	LTNF-10
LTNF-n	12800	12800	12800
LTNF-15	800	1600	600
LTNF-10	800	400	1600
<i>C. atrox</i> venom	600	600	800
<i>N. n. Kaouthia</i> venom	800	400	400
<i>R. viper</i> venom	3200	1600	1600
<i>O. scutellatus</i> venom	300	600	600
Scorpion venom	600	600	800
Bee venom	7200	1600	1600
Ricin	600	300	800
Cobratoxin	1600	1600	3200
Phospholipase (PhLA2) toxin	800	800	1600
Taipoxin	1600	1600	3200

Art Unit: 1645

The specification in the present application teaches that antibodies to N terminal LTNF-10 detect the toxin and it is an active domain of LTNF-n. However, the specification fails to teach antibodies to at least five amino acids of SEQ.ID.NO: 1 (viewed as any random five amino acids of SEQ.ID.NO: 1) binds to toxin and thereby could detect free toxin or toxin in a biological sample. Thus, the specification lacks support for the full scope of the invention as claimed.


Remarks

8. No claims are allowed.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

 9/1/04.


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600